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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,576	09/29/2004	Kazunori Kataoka	2004-1545A	2488

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EXAMINER

HAQ, SHAFIQUL

ART UNIT PAPER NUMBER

1641

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/509,576	Applicant(s) KATAOKA ET AL.	
	Examiner Shafiqul Haq	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendments filed April 20, 2006 is acknowledged and entered.
2. Claims 1-15 are pending.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker (US 2003/0157732 A1) in view of Barry et al (US 2004/0126900 A1).

Baker et al. disclose a biosensor system in which colloidal Au nanoparticle is functionalized with two different functional moieties (e.g. streptavidin and protein of interest) which is then contacted with a biosensor surface coated with biotin to form a colloid based biocompatible surface (see abstract; fig. 20 and paragraph [0134]). Baker also disclose BSA and streptavidin coated colloidal Au nanoparticle (i.e. nanoparticle with two different functional moieties) that is bound to biotin coated surface (see fig. 1C). Baker et al. also disclose that substrate is selected from group consisting of glass, alumina, tin oxide and metals (see claim 2) and the substrate can be coated with bifunctional organic groups selected from the group consisting of organosilanes, polyamine hydrochloride avidin and biotin to impart the substrate a functionality that allows for bonding of metal colloid particles (see claims 10 and 15).

The colloid nanoparticle can be selected from gold and silver and is functionalized with groups selected from organosilane, poly(allylamine) hydrochloride or a biotin (see claims 7-10).

Baker et al., however, fail to disclose nanoparticles having functional group or moiety with PEG linker.

Barry et al in a method to produce water soluble nanoparticle, disclose nanoparticles linked to biomolecular target via a linker molecule (see abstract). The linker can be a bifunctional PEG linker terminated with same or different reactive functional moieties, with one end attached to nanoparticle and the other end functionalized with a affinity peptide or biomolecular target (paragraphs [0011] and [0054-0056]). Barry et al also disclose that it is beneficial to functionalize the nanoparticle surface with PEG chain (lines 6-8 of paragraph [0054] as PEG is well-known in the art to impart water solubility and help reducing nonspecific binding.

Therefore, given the fact that PEG linker is common and known in the art to link functional moieties (e.g. binding partner/pair) to nanoparticle and PEG linker is beneficial to functionalize nanoparticle surface (Barry et al), it would have been obvious at the time of the invention to a person of ordinary skill in the art to use PEG linker to link functional groups or moieties on nanoparticle in the biosensor system of Baker et al. to impart water solubility to nanoparticle and to reduce nonspecific binding, with a reasonable expectation of success.

As for dependent claim 9, Baker et al. disclose size of metal particles lies within the range of 3-100 nm.

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5. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker (US 2003/0157732 A1) in view of Katoaka et al (US 2004/0038506 A1).

Baker et al. disclose a biosensor system in which colloidal Au nanoparticle is functionalized with two different functional moieties (e.g. streptavidin and protein of interest) which is then contacted with a biosensor surface coated with biotin to form a colloid based biocompatible surface (see abstract; fig. 20 and paragraph [0134]). Baker also disclose BSA and streptavidin coated colloidal Au nanoparticle (i.e. nanoparticle with two different functional moieties) that is bound to biotin coated surface (see fig. 1C). Baker et al. also disclose that substrate is selected from group consisting of glass, alumina, tin oxide and metals (see claim 2) and the substrate can be coated with bifunctional organic groups selected from the group consisting of organosilanes, polyamine hydrochloride avidin and biotin to impart the substrate a functionality that allows for bonding of metal colloid particles (see claims 10 and 15). The colloid nanoparticle can be selected from gold and silver and is functionalized with groups selected from organosilane, poly(allylamine) hydrochloride or a biotin (see claims 7-10). Baker et al. also disclose that the size of metal particles lies within the range of 3-100 nm.

Baker et al., however, fail to disclose nanoparticles having functional group or moiety with PEG linker.

Katoaka et al. disclose nanoparticle with a polymer having PEG unit and functional group to attach to nanoparticle and biomolecular targets (see abstract and paragraphs [0004], [0010], [0015], [0023], [0045]). The polymer disclosed by

Katoaka is the same as the polymer of claim 1 of present invention. Kataoka et al also disclose that dispersion stability is improved by using functionalized PEG derivative on metal particles (paragraph [0010]).

Therefore, given the fact that PEG linker is common and known in the art to link functional group or moieties (e.g. binding partner/pair) to nanoparticle, it would have been obvious at the time of the invention to a person of ordinary skill in the art to use PEG linker to link functional groups or moieties on nanoparticle in the biosensor system of Baker et al., with the expectation of producing PEG modified nanoparticle based biosensor useful for detection of analytes in a sample by various competitive and noncompetitive assays.

Response to Argument

6. Applicant's amendments and arguments filed 4/20/06 have been fully considered, and are persuasive to overcome the rejections under 35 USC 112, 35 USC 103 and the double patenting rejection of 10/20/05. However, Applicants' amendments ("wherein X and Y are not the same") necessitated new search and new ground of rejections, which are described in paragraphs 4-5 of this office action.

Conclusion

7. Applicant's amendment ("wherein X and Y are not the same simultaneously") necessitated the new ground(s) of rejection presented in this Office action. **THIS**

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ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

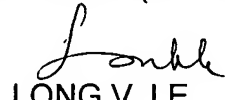
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


SHAFIQUL HAQ
EXAMINER
ART UNIT 1641

 07/21/05
LONG V. LE
SUPERVISORY PATENT EXAMINER
ART UNIT 1641